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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/847,703	05/01/2001	Mark W. Kroll	A01PI028	6988
36802	7590	08/20/2004	EXAMINER	
PACESETTER, INC. 15900 VALLEY VIEW COURT SYLMAR, CA 91392-9221			OROEZA, FRANCES P	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 08/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/847,703

Applicant(s)

KROLL, MARK W.

Examiner

Frances P. Oropeza

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/15/04 (Response & RCE).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/26/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. The Applicant's submission filed on 4/15/01 has been entered.

Claim Rejections - 35 USC § 102

2. Claims 1, 16-18 and 25-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Limousin (US 6181968). Limousin discloses a system to verify capture and to deliver pacing pulses to a combined electrode pair located in both ventricles / both atria (abstract; col. 1 @ 5-20; col. 2 @ 6-26; col. 3 @ 7-12).

Claim Rejections - 35 USC § 103

3. Claims 2-6, 19 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Limousin (US 6181968) in view of Weinberg et al. (US 5476485). As discussed in paragraph 2 of this action, Limousin discloses the claimed invention except tip stimulation electrodes (claims 2, 22), selecting polarities and electrode configurations (claims 3, 6, 19, 22), and biphasic and unipolar pacing (claims 4, 5).

Weinberg et al. teaches impedance detection and capture detection.

As to electrode selection/ configuration and pacing mode adjusted by polarity, configuration, Weinberg et al. teach cardiac stimulation and sensing using tip electrodes to stimulate, ring electrodes to sense/ pace (given the requirements of the unipolar/ bipolar pacing mode) for the purpose of providing system flexibility and teach control of the polarity of the electrodes during stimulation and sensing for the purpose of providing directional control for the stimulation and sensing. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used tip electrodes to stimulate, ring electrodes to sense and pace, unipolar and bipolar pacing modes, and control of the polarity of stimulation and sensing electrodes in the modified Limousin system in order to provide the hardware and associated system controls of the stimulation and sensing so the cardiac dynamics can be more precisely understood and by optimal stimulation, the cardiac output can be optimized (abstract; col. 1 @ 7-13; col. 4 @ 20 – col. 5 @ 25; col. 5 @ 31-40; col. 6 @ 10-11 and 40-42).

4. Claims 7-15, 20, 21, 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Limousin (US 6181968) in view of Weinberg et al. (US 5476485) and further in view of Salo et al. (US 6278894). As discussed in paragraphs 2 and 3 of this action, modified Limousin discloses the claimed invention except using impedance to monitor capture (claims 11 and 21) and using different electrode configurations to verify capture (claims 7-9, 12-15, 20, 23 and 24).

As to monitoring capture via impedance (claims 11 and 21), Salo et al. teach capture monitoring/ monitoring evoked change using impedance for the purpose of determining cardiac output. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used capture monitoring via impedance in the modified Limousin system in

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order to provide a proven means for precisely determining cardiac output so the stimulation energy can be more precisely optimized to provide optimal cardiac perfusion for the patient (col. 3 @ 31-65; col. 4 @ 21-33).

As to electrode configurations and claims 7-10, 12, 13, 20, 23 and 24, Salo et al. teach stimulation and sensing configurations using combinations of tip and ring electrodes for the purpose of stimulating cardiac tissue and sensing evoked responses. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used the multiple electrode stimulating and sensing configuration in the modified Limousin system in order to use a proven means that enables optimization of stimulation and sensing so the cardiac performance of the patient is optimized (abstract; figure 1; col. 1 @ 6-10; col. 2 @ 49-62; col. 3 @ 32-65; col. 4 @ 21-32; col. 4 @ 66 – col. 5 @ 3; col. 5 @ 23-27, 43-53 and 54-65).

As to electrode configurations and claims 14-15 and 24, Salo et al. teach cardiac diagnosis and therapy using multiple stimulation and sensing configurations for the purpose of maximizing the understanding of cardiac dynamics to enable selection of stimulation configurations that optimize cardiac output (col. 3 @ 32-65). This statement provides a clear suggestion that electrodes included in the stimulation pair and in the sensing pair can be modified to optimize the understanding of the cardiac tissue dynamics, hence enabling stimulation that improves cardiac output. The variation in the stimulation and sensing configurations is read to include stimulating with first and second left electrodes and sensing with first and second right electrodes, and sensing with left atrial and right ventricular electrodes. The determination of the most appropriate stimulation and sensing configurations by routine

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experimentation would, therefore, be prima facie obvious to one having ordinary skill in the cardiac stimulation and monitoring art.

Statutory Basis

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

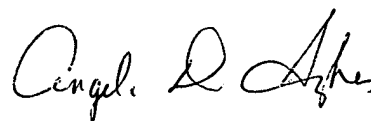
Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza, telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Friday from 9 a.m. to 5:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306 for regular communication and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist, telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762



ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
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